**Werley, Michael S**

**From:** Woiwode, Michaela on behalf of Roemer, Ewald
**Sent:** Wednesday, March 19, 2003 5:56 AM
**To:** Patskan, George J.; Werley, Michael S
**Cc:** Haussmann, Hans-Juergen; Reininghaus, Wolf
**Subject:** SDS on EHCSS-JLI

Dear George:
Dear Mike:

Please find attached several handwritten notes from Wolf. If there are difficulties to decipher them (as I expect), please give me a call and we will go through the notes.
My comments have already been incorporated into Hans-Jürgens comments.
The most important deficiency regarding the non-clinical data (chemistry, in vitro, and in vivo) in my view is that these data are given only as yields or activities per cigarette, mg TM, or whatever. A decreased yield/activity, however, is not sufficient for an exposure reduction claim, it has to be folded with the actual smoke intake. For instance, a decrease in Ames activity from 1,000 revertants/mg TPM to 500 is fine in itself but when there is an increase in TPM uptake by the smoker by a factor of 3 it resembles a disaster. The SDS in its current version does not only fail to comment on this but even does not allow the reader to make his own calculations on this.

Best regards,
Ewald

SDS_COMMENTS.pdf

HAUSSMANN

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